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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,783	01/17/2001	Gloria Elena Leon Paz De Rodriguez	034621-0102	7176

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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 11/23/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/764,783

Applicant(s)
Paz De Rodriguez

Examiner
Arun Chakrabarti

Art Unit
1655



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 30, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for identifying any change in the body of a human being caused by any physiological or pathological condition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Court in *re Wands*, 8 USPQ2d 1400 (CA FC 1988) stated with regard to enablement that

“Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”

Here, the claim is broadly drawn to a method for identifying any change in the body of a

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human being caused by any physiological or pathological condition. However, the specification does not provide guidance commensurate in scope with this claim; only generically teaches the detection of DNA from pregnant woman, breast cancer and cervical cancer. The specification provides no guidance regarding methods for identification of any other change in the body of a human being caused by any other physiological or pathological condition and no guidance has been provided to detect DNA patterns in male patients. There are only three working examples of such testing with pregnant woman, breast cancer and cervical cancer. It is highly unpredictable whether or what other disease would be detected by identifying DNA extracted from blood. This unpredictability arises from the following facts: (1) DNA patterns even from the same pregnant woman are not reproducible as shown in the Figures 2A-3E of the specification, (2) There is no correlation between the disease or physiological changes and the DNA pattern, (3) There is no S.E.M. value to determine the degree of significance of the DNA pattern (p-value as usually determined by Student's t-test), (4) Control or normal DNA pattern is lacking in all the experiments which is an essential requirement of studying and comparing the detection of diseases, (5) Phenol extraction strips off all proteins from the tissue and causes some loss of nucleic acids, and (6) DNA structure would be expected to vary depending on the phase (e.g., apoptotic, G2, G1, M and S would definitely show different patterns of DNA) and development of the cell. Thus, given these many unpredictable and, at least in the specification, non reproducible data, no correlation between any specific result has been shown. For example, no correlation between breast cancer and a control nuclear morphology has been shown which

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properly supports the unpredictability elements discussed above. Without such a correlation, based on proper controls, and statistically significant data, the method will not predictably detect or function to detect any particular disease state. It would require a large amount of experimentation, potentially including the processing of blood in thousands of patients and diseases, physiological abnormalities and pathological conditions, in order to identify additional DNA pattern with the claimed functionality. Given the Wand's factors opposing the full scope of enablement including the limited teaching in the specification, the presence of only pregnant woman, breast cancer and cervical cancer studies without any S.E.M. value to determine the degree of significance (p-value as usually determined by Student's t-test), the teaching of unpredictability in the prior art, the unpredictability of the art, the breadth of the claim, and the large amount of experimentation needed, with only the skill level in the art being neutral towards enablement, it is concluded that undue experimentation is necessary to make and use the invention as broadly claimed. Moreover, the claimed utility of identifying a change in the body of a human being caused by a physiological or pathological condition is not enabled by any supportive evidence provided in the specification.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-5 are rejected over the recitation of the phrases, "one volume", "two volumes", "four volumes" and "twenty-five volumes". It is not clear in claim 1, volumes are compared to what. The metes and bounds of the claims are vague and indefinite.

Claims 1-10 are rejected over the recitation of the phrase, "allow". Regarding claims 1 and 6, the phrase "allow" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Claims 1-10 are rejected over the recitation of the phrase, "can be used". Regarding claims 1 and 6, the phrase "can be used" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Claims 3, 4, 8 and 9 are rejected over the recitation of the phrase, "approximately 11,000 rpm". It is not clear if 9,900 rpm is claimed or 11,000 rpm is claimed or 12,100 rpm is claimed. The metes and bounds of the claims are vague and indefinite.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Arun Chakrabarti
Patent Examiner
Art Unit 1655,
June 11, 2001



JEFFREY FREDMAN
PRIMARY EXAMINER